

**REMARKS**

Claims 1 and 37-95 are pending. Claims 2-36 are cancelled without prejudice or disclaimer. Claims 1, 37, 42-43, 54-56, 65, 69-72, 79, 81-85, and 89 are amended. No new matter has been added to the claims.

***Claim Objections:***

On page 2 of the Office Action, the Examiner has objected to claims 42, 65-78, 82-84, 89, 90, 92, 93, and 95 for various informalities.

The Examiner has objected to claims 1, 37-80, 82-84, and 89-95; claims 42, 65-78, 89, 90, 92, 93, and 95; and alleged that the claims lack proper antecedent basis from the specification for using a "Three-cup prosthesis of shell, acetabular cup, and a femur cup." Applicants respectfully disagree with the Examiner. In response, applicants reiterate that the application is a continuation of the parent application PCT/US99/16070 and claims are supported by the specification (see for example, page 8, lines 24-26; page 9, lines 2-5; Figure 1; page 15, lines 8-12; Figure 8; and Figure 9). Applicants specifically indicate that "shell" and "acetabular cup" are described, for example, on page 8, lines 24-26 and page 9, lines 2-5; and "femur cup" and "acetabular cup" are described, for example, on page 15, lines 8-12.

Regarding upper limits in claims 1, 37-72, 79, 80, 82-84, and 89-95, applicants amend claims 1, 37, 42-43, 54-56, 65, 69-72, 79, 81-84, and 89 in the manner suggested by the Examiner.

The Examiner also has alleged that the claims "lack proper antecedent basis from the specification." Applicants state that claims are fully supported by the specification and refer to responses and arguments as set forth herein.

See for example, specification support for claimed terms, for example, "shell", "acetabular cup", and "femur cup" can be found in the specification (see for example, page 8, lines 24-26; page 9, lines 2-5; Figure 1; page 15, lines 8-12; Figures 8 and 9). More specifically, applicants indicate that "shell" and "acetabular cup" are described in the specification, for example, on page 8, lines 24-26 and page 9, lines 2-5; and "femur cup" and "acetabular cup" are described, for example, on page 15, lines 8-12.

In view of the above and clear support in the specification, withdrawal of the objections is earnestly requested.

***Claim Rejections:***

**Indefiniteness Rejections**

On page 3 of the Office Action, the Examiner has rejected claims 81-88 for indefiniteness. In response, applicants amend claims 81-85 for additional clarity.

Regarding claims 81-88, applicants amend the independent claim 81 by addition of "to accommodate a ball having a diameter of up to about 70 mm" to specify claimed dimensions of the upper limit of the pelvic socket. The amendment to the claim has support in the specification (see for example, page 10, lines 18-21).

Withdrawal of the rejections is respectfully requested.

**Obviousness Rejections**

The examiner has rejected the claims over various combinations of Graham *et al.* (U.S. Patent No. 5,549,700); Townley *et al.* (U.S. Patent No. 6,096,084); McKellop *et al.* (U.S. Patent No. 6,165,220); DeCarlo *et al.* (U.S. Patent No. 4,524,467); and Teinturier *et al.* (U.S. Patent No. 4,385,405). Applicants respectfully traverse these rejections.

At the outset, applicants note that the examiner must show all of the recited claim elements in the combination of references that make up the rejection. When combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by citation to specific evidence in the cited references that (i) there was a suggestion/motivation to make the combination and (ii) there was a reasonable expectation that the combination would succeed. Both the suggestion/motivation and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *W.L. Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (holding that it is improper in combining references to hold against the inventor what is taught in the inventor's application); see also MPEP §§ 2142-43 (Rev. 1, February 2003). Thus, the examiner must provide evidentiary support based upon the contents of the prior art to support all facets of the rejection, rather than just setting forth conclusory statements, subjective beliefs or unknown authority. See *In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002).

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper

(for example, there is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for example, unexpected results). See *U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). The references are discussed with these legal concepts in mind.

First, applicants refer to the arguments submitted in response to the Office Action of September 24, 2003 (Paper No. 7) and reiterate that: Graham does not teach the femur cup that can accommodate a femur head of 35 mm or greater; and Graham uses conventional UHMWPE.

Although McKellop mentions cross-linked UHMWPE, there is no disclosure supporting a cup that can accommodate a head of 35 mm or greater. Moreover, there is no motivation in McKellop to combine with Townley or DeCarlo or Teinturier. In countering applicants' previous arguments, the Examiner contended on page 7 of the Office Action that the "motivation is provided by McKellop in the abstract for crosslinking the polyethylene." However, Applicants reiterate that McKellop does not provide any motivation to crosslink a polyethylene for use in a cup that can "accommodate a head of 35 mm or greater," particularly given McKellop's reliance on smaller cups and head sizes, discussed below, which has not been addressed by the examiner.

More particularly, the McKellop patent discloses "surface-crosslinked UHMWPE acetabular cups of 32 mm" (see column 17, lines 3-4). However, McKellop does not describe acetabular cup having diameter of 35 mm or more, nor that the "crosslinked UHMWPE" could be used to make wear resistant acetabular cups that can accommodate femur head of diameter larger than 32 mm. According

to McKellop "PE powder is placed in an implant mold and compression molded using methods known in the art to a slight oversize of the I.D. [inner diameter] to allow for the addition of a crosslinked layer" (see Column 9, lines 65-67). Therefore, McKellop reinforces the bias in the filed for smaller heads and teaches away from making acetabular cup having diameter larger than 32 mm using the "crosslinked UHMWPE." (emphasis added).

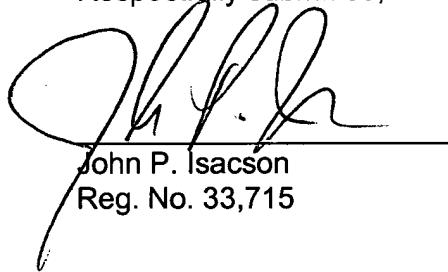
Withdrawal of the rejections is therefore solicited.

Additionally, Applicants submit herewith a declaration from Dr. William Harris, who provides an explanation of the state of the art prior to the filing of the captioned patent application, and the deficiencies in the combination of references made by the examiner. The Harris declaration is self-explanatory, and requires no further discussion here. Therefore, the Harris declaration provides still further evidence of the patentability of the claimed invention.

**REQUEST**

In view of this Amendment and Applicants' remarks above, Applicants respectfully submit that claims 1 and 37-95 are allowable, and respectfully request favorable consideration to that effect. If any additional fees or additional extensions of time are required with the filing of this Amendment, Applicants respectfully request such fees and extensions be charged to Deposit Account No. 08-1641. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,



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